

REMARKS

Claims 9, 18, 23, 26-28, 30, 32 and 34 are pending in the application. Claims 9, 18 and 30 have been amended. No new matter has been added.

Initially, Applicant would like to thank the Examiner for taking time to discuss the pending Application and cited art with Applicant's undersigned representative on October 12<sup>th</sup>, 2005 in an effort to advance prosecution of the Application. As discussed during the telephonic interview, Applicant has amended the independent claims to more clearly cite the positioning of the rear support pad. As discussed below in detail, Applicant has also reiterated his reasoning behind his position that, despite the amendments to the claims that Applicant believes place the claims in condition for allowance, the cited art is not in a field analogous to that of the present invention.

Claims 9, 18 and 30 are independent.

**CITED ART IS NOT IN A FIELD ANALOGOUS TO THAT OF THE PRESENT INVENTION**

On pages 2-8 of the Office Action, all of the pending claims were rejected under 35 U.S.C. §103, as obvious. The references cited in the rejections include combinations of Inhat (U.S. Patent No. 3,588,914), El Hassen (U.S. Patent No. 4,646,367), Steffen (U.S. Patent No. 3,171,133) and Simpson (U.S. Patent No. 3,039,109). Applicant respectfully objects to the application of the references cited in the Office Action against Applicant's claimed invention. In order to properly rely on a reference under 35 U.S.C. §103, Applicant respectfully reminds the Examiner that the reference must be analogous prior art, where "the reference must either be in

the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned," *In re Oetiker*, 977 F. 2d 1443 (Fed. Cir. 1992), as cited in MPEP §2141.01(a). Both the specification and the claims of Applicant's invention clearly contemplate and provide an apparatus and method for treating a medical condition, namely, deformational plagiocephaly, on the head of an infant. The cited references of Inhat, Jr., El Hassen , Steffen and Simpson each disclose a protective device whose purpose it is to prevent injury from forceful impacts that may be experienced in sports or other potentially injurious activity. Applicant makes no reference or disclosure towards preventing or protecting against injury, just as the cited references make no mention of providing therapeutic benefits, let alone treating a specific condition. The Office Action improperly characterizes the cited protective devices as inherently and obviously including support characteristics, when in fact the cited references specifically provide for protection against trauma. As such, Applicant believes it to be improper to cite the above-mentioned references as they constitute non-analogous art that is irrelevant to the field of the endeavor and particular problem with which Applicant's claimed invention is concerned.

**NO MOTIVATION TO COMBINE OR COMBINE REFERENCES IS PROVIDED IN THE OFFICE ACTION**

Moreover, the Office Action states in each of the rejections that it would have been obvious to make modifications to the cited references in order to obtain Applicant's claimed invention. Applicant reminds the Examiner that the requisite motivation to modify a reference must be derived from the applied prior art. Each of the Inhat, Jr., El Hassen, Steffen and Simpson references, however, are silent as to any suggestion that such devices can be used to provide treatment for a medical condition, and are similarly silent as to providing support for the head of an infant.

Furthermore, the Office Action has failed to explain how or why the various protection devices of Inhat, Jr., El Hassen, Steffen and Simpson would be modified to provide for an infant positioning system for treatment of any medical condition, let alone deformational plagiocephaly.

Given the lack of factual support within Inhat, Jr., El Hassen, Steffen and Simpson for the Office Action's asserted motivation to modify the various references, Applicant can only conclude that the Examiner has engaged in impermissible hindsight reconstruction based upon Applicant's teachings so as to arrive at the claimed invention. Since the Office Action has failed to assert a proper motivation to modify the references cited, Applicant submits that the Office Action does not establish a prima facie basis to deny patentability to the claimed invention under 35 U.S.C. § 103 for lack of the requisite realistic motivation. Applicant, therefore, respectfully solicits withdrawal of the imposed rejections of Claims 9, 18, 23, 26-28, 30, 32 and 34 under 35 U.S.C. § 103 for obviousness.

**APPLICANT'S DISCUSSION REGARDING SPECIFIC REJECTIONS**

On page 2 of the Office Action, Claims 18, 23, 26-28, 30 and 34 were rejected under 35 U.S.C. §103(a) as being unpatentable over Inhat, Jr. '914 in view of any of El Hassen '367 or Steffan '133 or Simpson '109. Claim 18, as amended, recites in part a headgear having a second support pad, "wherein the second support pad is positioned about the rear of the headgear to locate the opening about a flattened area on the head of the infant." Similarly, Claim 30, as amended, states a method of using a headgear to treat deformational plagiocephaly, including the step of "attaching the selected at least one second support pad to the rear of the headgear such that the opening of the second support pad overlays a flattened area on the head of the infant." None of the cited references teach or suggest this feature.

In addition, the Office Action states that it would have been obvious to have formed the Inhat, Jr. headgear as to allow for removably attaching the toroidal support cushion pad along a rear portion of the headgear as taught by any of El Hassen, Stefan or Simpson.

However, the toroidal cushions of Inhat. Jr. '914 are specifically shaped to integrate with ear protectors 20 and 22, which "protectively cover the ears of the wearer and smoothly protrude from headpiece 10 so as to present minimal interference," (Col. 4, Lines 9-11). Primarily, as the toroidal cushions of Inhat Jr. '914 are shaped to conform to the ears, there would be no reason or motivation to move the cushions to the rear of the head, as obviously there are no ears located there. In addition, El Hassen '367 discloses a tumbling cap having a plurality of rectangular padded parts "designed to protect small children's heads against knocks," (Col. 1, Lines 9-11), while Steffen '133 provides a protective helmet having a pad-like frontal member and a posterior member, where the posterior member "provides complete protection over the bitrachion-posterior arc...and the bitrachion-inion arc," (Col. 2, Lines 50-56), that is to say, the posterior member covers substantially all of the back of the skull. Similarly, the Simpson '109 reference discloses "a liner construction for safety helmets, which liner is in the form of fluid filled cushions which provide a high degree of protection against very severe impact such as occurs in crash landings," (Col. 3, Lines 4-8).

As such, to position the toroidal cushion of Inhat Jr. '914 as shown in any of the El Hassen '367, Steffen '133, or Simpson '109 references would be contradictory to the teachings of those references. Positioning a toroidal cushion on the rear of the head would expose a portion of the skull through the opening in the cushion, thus subjecting the exposed portion to injury, which is exactly what the El Hassen '367, Steffen '133, and Simpson '109 references are

focused on preventing. In addition, even if the cited references were properly combined, they make no mention of positioning the toroidal cushion such that the opening overlays “a flattened area on the head of the infant,” as stated in Claims 18 and 30.

Subsequently, for the reasons stated above, amended Claims 18 and 30 are believed to have overcome the rejection under 35 U.S.C. §103(a), and are thus believed to be allowable. Applicant therefore respectfully requests the withdrawal of the rejection of these claims.

Moreover, Claims 23, 26-28 and 34 are believed to be allowable over the rejection under 35 U.S.C. §103(a) as they depend from independent amended Claims 18 and 30.

On page 4 of the Office Action, Claim 32 was rejected under 35 U.S.C. §103(a) as being unpatentable over Inhat, Jr. ‘914 in view of any of El Hassen ‘367 or Steffan ‘133 or Simpson ‘109, and further in view of any of Alivizatos ‘403, Painter ‘784, Ross ‘65, and Brady et al. ‘924. Claim 32 is dependent from amended independent Claim 30, and is thus believed to be allowable.

On page 5 of the Office Action, Claims 9, 30 and 34 are rejected under 35 U.S.C. §103(a) as being unpatentable over Inhat, Jr. ‘914 in view of any of El Hassen ‘367 or Steffan ‘133 or Simpson ‘109, and further in view of Bridley ‘832. A feature of Claim 9, similar to Claims 18 and 30 discussed above, is “at least one second support pad having an opening therethrough, the second support pad being removably attachable to the headgear, wherein the at least one second support pad is positioned about the rear of the headgear to locate the opening about a flattened area on the head of the infant.” For the reasons stated above regarding the rejection to Claim 18 in view of the Inhat, Jr. ‘914, El Hassen ‘367, Steffen ‘133 and Simpson ‘109, Claim 9 is believed to be allowable as the cited references are non-analogous art which have lack any

motivation to combine. Further, even if properly combined, the cited references do not disclose the above-recited feature, namely, “the at least one second support pad is positioned about the rear of the headgear to locate the opening about a flattened area on the head of the infant.”

Moreover, page 5 of the Office Action states that “one of ordinary skill in the art would have found it obvious, if not intrinsic, to have positioned an infant wearing the supplementary headgear upon the surface of the infant support device.” The Bridley ‘832 reference discloses “an infant support which permits an infant to sleep on its side, but which is comfortable and not constricting,” (Col. 2, Lines 2-4). Clearly, placing an infant on the infant support device of Bridley ‘832 while wearing the “protective sports headgear” of Inhat Jr. ‘914, the “tumbling cap” of El Hassen ‘367, the “protective helmet” of Steffen ‘133, or the “safety helmet” for “crash landings or the like” of Simpson ‘109 would neither allow the infant to sleep on its side, nor would it provide “comfortable and not constricting” sleep, further evincing the impropriety of combining the cited references.

Subsequently, for the reasons stated above, amended Claims 9 and 30 are believed to have overcome the rejection under 35 U.S.C. §103(a), and are thus believed to be allowable. Applicant therefore respectfully requests the withdrawal of the rejection of these claims.

In addition, Claim 34 is believed to be allowable over the rejection under 35 U.S.C. §103(a) as it depends from independent amended Claim 30.

On page 5 of the Office Action, Claim 32 was rejected under 35 U.S.C. §103(a) as being unpatentable over Inhat, Jr. ‘914 in view of any of El Hassen ‘367 or Steffan ‘133 or Simpson ‘109, and Bridley ‘832, and further in view of any of Alivizatos ‘403, Painter ‘784, Ross ‘65, and

Brady et al. '924. Claim 32 is dependent from amended independent Claim 30, and is thus believed to be allowable.

On Page 6 of the Office Action, Claims 18, 23, 26, 28 and 30 were rejected under 35 U.S.C. 103(a) as being unpatentable over El Hassen '367 in view of Clavelle '840 and either of Simpson '109 or Inhat Jr. '914. A feature of independent Claim 18, as amended, includes a headgear having a second support pad, "wherein the second support pad is positioned about the rear of the headgear to locate the opening about a flattened area on the head of the infant." Similarly, independent Claim 30, as amended, recites a method of using a headgear to treat deformational plagiocephaly, including the step of "attaching the selected at least one second support pad to the rear of the headgear such that the opening of the second support pad overlays a flattened area on the head of the infant." El Hassen '367 discloses a tumbling cap designed to protect small children's heads, while Clavelle '840 discloses a skin heat shield system "that shields the forehead, neck and ears of a person receiving hair care treatments," (Col. 1, Lines 25-27).

As stated above, the E Hassen, Simpson and Inhat Jr. references are nonanalogous art. In addition, there is simply no motivation to combine the Clavelle '840 reference with the El Hassen '367 reference, as heat shielding during hair treatment is completely irrelevant to protecting against "knocks on forehead, sides, and back of head," as taught by El Hassen '367. There is no teaching in the Clavelle reference that would motivate one to combine a heat shield with impact protection headgear. Furthermore, even assuming such a combination is proper, to position a toroidal cushion about the rear of the headgear, as recited in Claims 18 and 30, would

undermine the very goal which El Hassen, Simpson, and Inhat Jr. are focused on achieving, that is, to prevent injury.

The Office Action further states on Page 7 that "it would have been further obvious...to have utilized the modified El Hassen cap with an infant/child...to provide for comforting sleep or, at least, comfortable rest as well as to protect the child during sleep or rest." This statement exemplifies the apparent confusion in the Office Action regarding Applicant's field of endeavor. Neither Applicant's claims nor disclosure mentions providing comfortable sleep, nor of protecting the child during sleep. Applicant's claimed invention is for therapeutic treatment of a medical condition.

Subsequently, for the reasons stated above, amended Claims 18 and 30 are believed to have overcome the rejection under 35 U.S.C. §103(a), and are thus believed to be allowable. Applicant therefore requests that the rejections to these claims be withdrawn.

Claims 23 and 26-28 are likewise believed to be allowable over the rejection under 35 U.S.C. §103(a) as they depend from independent amended Claim 18.

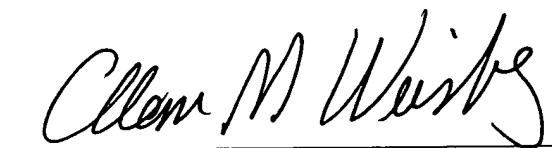
On page 8 of the Office Action, Claim 32 was rejected under 35 U.S.C. §103(a) as being unpatentable over El Hassen '367 in view of Clavelle '840 and either of Simpson '109 or Inhat Jr. '914, and further in view of any of Alivizatos '403, Painter '784, Ross '65, and Brady et al. '924. Claim 32 is dependent from amended independent Claim 30, and is thus believed to be allowable.

For all of the above reasons, the claim objections are believed to have been overcome, thereby placing Claims 9, 18, 23, 26-28, 30, 32 and 34 in condition for allowance, and reconsideration and allowance thereof is respectfully requested.

The Examiner is encouraged to telephone the undersigned to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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